Attachment 8

NOV 0 5 2001

510(k) SUMMARY K012545

Lumedics's Aramis Dermatologic Laser

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Mitchell J. Robins
Lumedics, Ltd.
7567 La Jolla Blvd.
La Jolla, CA 92037
Phone: 858-794-6200
Facsimile: 858-551-1215

Contact Person: Mitchell J. Robins

Date Prepared: August 6, 2001

Name of Device and Name/Address of Sponsor

Lumedics Aramis Dermatologic Laser

Lumedics, Ltd.
7567 La Jolla Blvd.
La Jolla, CA 92037

Common or Usual Name

Dermatologic Laser

Classification Name

Powered Laser Surgical Instrument for use in General Dermatological Use

Product Code

GEX Panel: 79

Predicate Devices

Palomar Medical Technologies, Inc. Aramis Dermatologic Laser

Intended Use

The Aramis is intended to be used for incision/excision, ablation, and coagulation (homeostasis) of soft tissue. The Aramis Laser is also indicated for the photocoagulation of dermatological vascular lesions, including photothermolysis of blood vessels (treatment of facial and leg veins) and the treatment of benign pigmented lesions.

Technological Characteristics and Substantial Equivalence

The Aramis Dermatologic Laser is an Er-glass 1.54 µm system. The computer system consists of a laser unit, a cooler, a footswitch, and a 2mm or 4mm hand piece. The 4mm hand piece is gas-cooled to provide actual skin cooling. Laser parameters and other system features are controlled from the touch-buttons on top of the laser unit, which provides an interface to the system computer.

The Aramis is substantially equivalent to the currently marketed Palomar Aramis Dermatologic Laser powered surgical lasers in intended use, indications for use, principles of operation, and technological features. Any minor differences do not raise any new issues of safety or effectiveness.

Performance Data

The Aramis complies with 21 C.F.R. §§ 1040.10 and 1040.11, as well as the following voluntary performance standards:

- UL544; Electrical Leakage
- IEC 60-601-1; Power Supply and Enclosure
- IEC 60-825-01; Safety of Laser Product
- IEC 601-2-22; Therapeutic Laser Equipment Safety
- 93/42/EEC; European Directive
- IEC 60-601-1-2; Electromagnetic Compatibility

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 5 2001

Lumedics, Ltd.
c/o Mr. Jonathan S. Kahan, Esq.
Hogan & Hartson, LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K012545
Trade/Device Name: Lumedics, Ltd. Aramis Dermatologic Laser
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 6, 2001
Received: August 7, 2001

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker MD for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 9

NOV 0 5 2001

Indications for Use Form

510(k) Number (if known): K012545

Device Name: **Lumedics, Ltd. Aramis Dermatologic Laser**

Indications for Use:

The Aramis Dermatologic Laser system is intended to be used for incision/excision, ablation, and coagulation (homeostasis) of soft tissue. The Aramis Laser is also indicated for the removal of pigmented lesions; photocoagulation of dermatological vascular lesions, including photothermolysis of blood vessels (treatment of facial and leg veins).

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 C.F.R. 801.109)

OR Over-The-Counter Use____

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

(Optional Format 1-2-96)

510(k) Number K012545

\\\DC - 80829/2 - #1352220 v2